

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison of ischemic compression and dry needling as trigger point therapy for patellofemoral pain syndrome in young adults: A double-blind randomized clinical trial

#### Protocol summary

##### Summary

The aim of this study is to compare the effectiveness of ischemic compression (IC) directly to the knee versus dry needling (DN) in improving pain, functional status and sensitivity to mechanical stimulation in patients with patellofemoral pain syndrome (PFPS). 54 patients (according to pilot study) with unilateral PFPS aged 20-30 years will be randomly selected according to the inclusion-exclusion criteria among patients referred to physical therapy clinics of Babol University of Medical Sciences (single center) in Babol, Iran. The inclusion criteria contains reported pain of more than 6 weeks' duration, reported pain in one of the following tests: vastus medialis coordination test, patellar apprehension test, eccentric step test. Volunteers were excluded if they had a history of any of ligamentous insufficiency of the knee, spine or lower extremity surgery or trauma. A blinded examiner will divide participants into 2 groups by Systematic Random allocation, also patients would be blinded to treatment allocation. Patients in both groups will treat in three sessions per week alternatively. IC consist of three sets of continuous pressure applied for on the myofascial trigger point (MTrP) of VMO. DN consist inserting a stainless steel needle on the MTrP found in VMO until feel the first twitch. Main outcome measures include Numeric pain rating scale (VAS) for pain intensity, Kujala questionnaire for functional status, and pressure pain threshold (PPT) for sensitivity to mechanical stimulation. All three were recorded before treatment, 1 week, 1 month and 3 months after the last session.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016062028542N1**

Registration date: **2017-03-08, 1395/12/18**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-03-08, 1395/12/18

##### Registrant information

###### Name

Shabnam` Behrangrad

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 911 255 3309

###### Email address

dbehrang@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

investigator

##### Expected recruitment start date

2017-05-22, 1396/03/01

##### Expected recruitment end date

2017-06-20, 1396/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of ischemic compression and dry needling as trigger point therapy for patellofemoral pain syndrome in

young adults: A double-blind randomized clinical trial

### Public title

dry needling efficacy in patients on pain and function of patient with patellofemoral pain syndrome

### Purpose

Treatment

### Inclusion/Exclusion criteria

The inclusion criteria are: 1) reported pain of more than 6 weeks' duration in at least two of the following situations: patellar compression, squatting, prolonged sitting, walking, stair climbing, isometric quadriceps contraction (Crossley K et al 2002; Whittingham M et al 2004; Iverson et al 2008); 2) reported pain in one of the following tests: vastus medialis coordination test, patellar apprehension test, eccentric step test (Nijs J et al 2006); 3) presence of at least one MTrP in the VMO of the symptomatic knee (pressure applied to the VMO produced pain); 4) Kujala questionnaire score between 40 and 70, and visual analog scale (VAS) score greater than 40. Volunteers will be excluded if they had a history of any of the following: ligamentous insufficiency of the knee, meniscus damage, patellar subluxation or dislocation, nerve root compression, spine or lower extremity surgery, any systemic, orthopedic or neurological disorder, or current physical therapy (Iverson CA et al. 2008; Hains G and Hains F 2010; Grindstaff TL et al 2012).

### Age

From **20 years** old to **30 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **54**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Not used

### Assignment

Other

### Other design features

blocking method

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Babol University of Medical

Sciences

#### Street address

Babol

#### City

Babol

#### Postal code

#### Approval date

2017-01-19, 1395/10/30

#### Ethics committee reference number

MUBABOL.REC.1395.190

## Health conditions studied

### 1

#### Description of health condition studied

patellofemoral pain syndrome

#### ICD-10 code

M70.8

#### ICD-10 code description

Other soft tissue disorders related to use, overuse and pressure

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

before treatment, 1 week after treatment, 1 month after treatment, 3 months after treatment

#### Method of measurement

NPRS

### 2

#### Description

PPT

#### Timepoint

before treatment, 1 week after treatment, 1 month after treatment, 3 months after treatment

#### Method of measurement

digital algometry

### 3

#### Description

functional status

#### Timepoint

before treatment, 1 week after treatment, 1 month after treatment, 3 months after treatment

#### Method of measurement

kujala questionnaire

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group 1: ischemic compression: Treatment in this group involves applying tolerably painful, persistent manual pressure (usually with the thumb) against the tissue barrier of the MTrP. The examiner sustained the pressure for 90 seconds. Compression was performed three times in each session, with a 30-second rest between applications. Each patient in this group will receive 3 sessions of treatment per week alternatively. Main outcome measures were recorded before treatment, 1 week, 1 month and 3 months after the last session of treatment.

### Category

Rehabilitation

## 2

### Description

Intervention group 2: dry needling: the needle was inserted perpendicularly through the skin over the MTrP area, using the fast-in and fast-out technique and moved forward until a local twitch response was obtained. Each patient in this group will receive 3 sessions of treatment per week. Main outcome measures were recorded before treatment, 1 week, 1 month and 3 months after the last session of treatment.

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Babol university of medical sciences

##### Full name of responsible person

Shabnam Behrangrad

##### Street address

mazandaran, sari

##### City

Babol

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

investigator

##### Full name of responsible person

Shabnam Behrangrad

##### Street address

mazandaran, sari

##### City

Babol

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

investigator

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Mazandaran University of Medical Sciences

#### Full name of responsible person

Shabnam Behrangrad

#### Position

master of science

#### Other areas of specialty/work

#### Street address

mazandaran, sari

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dbehrang@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mazandaran University of Medical Sciences

#### Full name of responsible person

Shabnam Behrangrad

#### Position

master of sciences

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#### Street address

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## Person responsible for updating data

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Mazandaran University of Medical Sciences

**Full name of responsible person**

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master of sciences

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*